CATHETER WITH EXPANSION UNIT

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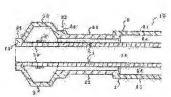
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Abstract of JP 8317969 (A)

PURPOSE: To eliminate possibility of leak or the like in a fused part by providing a catheter with an expansion unit, whose base end is fused and connected with the tip end of the outer tube, whose tip end is attached to the inner tube, and whose base end or the proximity communicates with the lumen, and thereby surely connecting the expansion unit with the outer tube. CONSTITUTION: The inner tube 1 is provided with a base end part, tip end part 12, first lumen 14 with an open end 13, and X-ray contrast marker 15 for showing the position of the expansion unit 3. The outer tube 2 is formed coaxially to the inner tube 1, equipped with a main body 21 and a tip end part 22, and arranged at a prescribed position 23, forming a second lumen 24. In addition, the tip end part 22 is composed of a noncross-linked olefin resin, the main body 21 is composed of a cross-linked olefin resin and both are fused. Further, the expansion unit 3 is fused at the base end part 32 with the tip end part 22 of the outer tube 2, with the tip end part 31 fused with the tip end 13 of the inner tube 1: the expansion unit is composed of a cross-linked olefin resin, having a bulged part communicating with the second lumen 24 in the proximity of the base end part 32.



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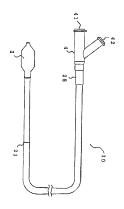
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(54) 【発明の名称】 拡張体付カテーテル

(57) 【要約】

【目的】拡張体と外管の接続部分にリークなどがなく、 確実な融着強度を有する拡張体付カテーテルの提供。 【構成】基端部と先端部を有し、先端が開口する第1の ルーメンを有する内管と、該内管に同軸的に設けられ、 本体部分と先端部分と有し、該内管の先端より所定長後 退した位置に設けられ、該内管の外面との間に第2のル ーメンを形成し、該先端部分は未架橋オレフィン系樹 脂、該本体部分は架橋オレフィン系樹脂からなり、該先 端部分と該本体部分は融着接続されている外管と、先端 部および基端部を有し、該基端部は前記外管の先端部分 と融着接続され、該先端部は前記内管に取り付けられ、 該基端部付近にて前記第2ルーメンと連通する収縮ある いは折り畳み可能な架橋オレフィン系樹脂からなる拡張 体と、該内管の基端部に設けられた前記第1のルーメン と連通する第1の開口部と、前記外管の本体部分の基端 に設けられた前記第2のルーメンと連通する第2の開口 部とを有する拡張体付カテーテルである。



【特許請求の節囲】

1 【請求項1】基端部と先端部を有し、先端が開口する第 1のルーメンを有する内管と、

該内管に同軸的に設けられ、本体部分と先端部分と有 し、該内管の先端より所定長後退した位置に設けられ、 該内管の外面との間に第2のルーメンを形成し、該先端 部分は未架橋オレフィン系樹脂、該本体部分は架橋オレ フィン系樹脂からなり、該先端部分と該本体部分は融着 接続されている外管と、

先端部および基端部を有し、該基端部は前記外管の先端 10 部分と融着接続され、該先端部は前記内管に取り付けら れ、該基端部付近にて前記第2ルーメンと連通する収縮 あるいは折り畳み可能な架橋オレフィン系樹脂からなる 拡張体と、

該内管の基端部に設けられた前記第1のルーメンと連通 する第1の開口部と、前記外管の本体部分の基端に設け られた前記第2のルーメンと連通する第2の閉口部とを 有することを特徴とする拡張体付カテーテル。

【請求項2】前記外管の本体部分の内側に金属補輪体を 設けたことを特徴とする請求項1に記載の拡張体付カテ ーテル。

【請求項3】前記金属補強体は管状であり、先端部がコ イル状であることを特徴とする請求項2に記載の拡張体 付カテーテル。

【発明の詳細な説明】

[0001]

【産業上の利用分野】本発明は心筋梗塞などの原因とな る心臓動脈の狭窄部位に挿入して拡張する手技に用いる 拡張体付きカテーテルに関する。

[00002]

【従来の技術】従来の血管内の狭窄部を拡張する拡張体 付カテーテルとしては、例えば、特開平3-73167 号公報に示されるものがある。この公報に記載の拡張体 付カテーテルの拡張体の取り付け状態は、図6に示すご とく、内管101と、この内管101と同軸的に設けら れた外管102と、内管101および外管102に取り 付けられた拡張体103とからなり、外管102と拡張 体103の接続は外管102の先端104と拡張体10 3の基端部105の融着しろ106、107を重ね合わ せた状態で加熱し、融着を行っている。

[0003]

【発明が解決しようとする課題】前述のカテーテルで は、外管と拡張体の融着強度が両者の材質により、大き く変わることがあった。また、オレフィン系樹脂からな る拡張体や外管は耐圧強度をあげるために、架橋されて いることがある。しかしながら、このような架橋オレフ イン系樹脂からなる材質同士を融着により接着した場 合、高い融着強度が望めず、リーク等が発生する戯れが あった。

るリーク等の虞れのなく、耐圧強度の拡張体付カテーテ ルを提供することを課題とする。

[0005]

【課題を解決するための手段】この課題は以下の (1) ~ (3) に示す本発明の拡張体付カテーテルによって解 決される。

【0006】(1)基端部と先端部を有し、先端が開口 する第1のルーメンを有する内管と、該内管に同軸的に 設けられ、本体部分と先端部分と有し、該内管の先端よ り所定長後退した位置に設けられ、該内管の外面との間 に第2のルーメンを形成し、該先端部分は未架橋オレフ ィン系樹脂、該本体部分は架橋オレフィン系樹脂からな り、該先端部分と該本体部分は融着接続されている外管 と、先端部および基端部を有し、該基端部は前記外管の 先端部分と融着接続され、該先端部は前記内管に取り付 けられ、該基端部付近にて前記第2ルーメンと連通する 収縮あるいは折り畳み可能な架橋オレフィン系樹脂から なる拡張体と、該内管の基端部に設けられた前記第1の ルーメンと連通する第1の開口部と、前記外管の本体部 分の基端に設けられた前記第2のルーメンと連通する第 2の開口部とを有する拡張体付カテーテル。

【0007】(2)前記外管の本体部分の内側に金属補 強体を設けた上記(1)に記載の拡張体付カテーテル。 【0008】(3)前記金属補強体は管状であり、先端 部がコイル状である上記(2)に記載の拡張体付カテー テル。

【0009】本発明の拡張体付カテーテルは上記(1) のように、架橋オレフィン系樹脂からなる拡張体の基端 部と、架橋オレフィン系樹脂からなる外管の先端部分は 30 融着により接続されている。これらの融着接続は、架橋 オレフィン同士と比較して、相溶性が高く、強固な融着 が実現できる。また外管は本体部分と先端部分の接着も 同様に架橋オレフィン系樹脂と未架橋オレフィン系樹脂 の融着からなっており、強固な融着となっており、未架 橋オレフィン系樹脂の先端部分を介して間接的ではある が、架橋オレフィン系樹脂の外管と架橋オレフィン系樹 脂の拡張体とを強固に接続することが可能となる。

【0010】ここで未架橋オレフィン系樹脂とは、オレ フィン系樹脂の未架橋体を示すだけでなく、わずかに架 40 橋したものも含むものであり、架橋オレフィン系樹脂よ りは架橋度が低いものも含むものである。

【0011】これらの融着接続は以下のようにして実現

【0012】1. 未架橋オレフィン系樹脂の外管の先端 部分に金属の芯金を通し、架橋オレフィン系樹脂の本体 部分の一部を重ね合わせる。この重なった部分が融着し ろとなる。

【0013】2、続いて融着しろの部分を覆うようにシ リコーン製熱収縮チューブを被せ、シリコーン製熱収縮 【0004】本発明はこのような低い融着強度に起因す 50 チューブの上から加熱する。シリコーン製熱収縮チュー

ブは熱収縮して融着しろを強く密着させた状態で、加熱 されるので、強い融着強度が得られる。

[0014] 3. 次に先端部分の先端に、拡張体の基端 部を重ね合わせ、重ね合わせ部分を融着しるとし、さら にシリコーン製熟収縮チェーブを被せた後、加熱する。 上記2と同様に強い融着強度の接触部が得られる。

【0015】このようにして簡単に融着強度の高い接続 を実現できる。

【0016】次に上記(2)のように外管の本体部分の 内側に金属補強体を設けたので、トルク伝達性も高く、 押し込み特性も向上する。

【0017]また、上記(3)のようた組織体を管状と し、先端はコイル状とした事により、耐キンク性に優れ るようになる。このような組織体を外管的に設ける方法 としては、予め外管の径をコイルよりも大きいものを準 備しておき、この外管内にコイルを挿入(ただし、先端 から所定の形分は融着しるとするために、コイルは挿入 しない)したのち、加熱すると、外管は収縮しコイルの 外表面に悪着した状態となる。外管と細胞体が完全に感 着することにより、トルク伝達性に優れ、耐キンク性も 20 向上し、操作性に優れるようになる。

[0018]

【実施例】以下、本発明の実施例を参照して発明の内容 を詳細に説明する。

[0 0 1 9]

【実施例1】図1は本発明の拡張体付カテーテル10の 全体図である。図2は拡張体付カテーテル10の拡張体 が付いた先端部分の拡大部分断面図である。

【0020】図に示すように拡張体付カテーテル10は 内管1、外管2、拡張体3と、基端に設けられたハブ4 30 とからなっている。

【0021】内管1は直径0.6mmで肉厚0.075 mm、長さ1500mmの高密度ボリエチレン製であ り、基端部と先端部12を有し、先端13が明コする第 1のルーメン14を有し、拡張体3の位置を示すため に、X線進影マーカー(プラチナコイル)15が設けら れている。

【0022】また、外管2は内管1に同軸的に設けられ、本体部分21と先端部分22と有し、本体部分の直径1.0万mm、長さ1270mm、先端部分の直径0.9mm、長さ80mmであり、肉厚は実に0.075mmである。また、内管1の先端13より所定長後退した位置23に設けられ、外管2の内面との間に第2のレーメン24を形成し、先端部分22は失業者オレフィン系樹脂(線状低密度ボリエチレン(エチレンーへキセン共重合体(CeLLDPE)))からなり、本体部分と1は実轄カナフィス条樹脂(線状低密度オリエチレン(エチレンーへキセン共重合体(CeLLDPE))の電子病楽器品)からなっており、両者は離者接続されている。

【0023】さらに、拡張体3は、先端部31および基端部32を有し、基端部32は外管2の先端部3分22と 能量物級され、先端部31は内管1の先端13に融音機 接続され、基端部32付近にて第2ルーメン24と 通過する収縮あるいは折り畳み可能な拡張部を有する架橋オレフイン系機能(線状低能度ボリエチレン (エチレンーへキセン共重合体(CeLLDPE))の電子線架橋高)からなっている。先端部31は外径が0.7 mmで、肉厚が0.15mmであり、基端部32は外径が1mで、肉厚が0.15mmであり。基端部32は外径が1mで、肉厚が0.15mmであり。其保部32は所収金に、15mmである。また、拡張部は拡張した時の外径が2.5mmである。数据体の全長は27mmである。拡張体の一般は26mである。

【0024】そして、ハブ4は、内管1の基端部に設けられた前記第1のルーメン14と運通する第1の関口部41と、外管2の本体部分21の基端に設けられた第2のルーメン24と連通する第2の開口部42とを有している。

用される部位によって、任意に変更が可能である。

【0025】またハブ4と外管2の本体部分21の基端の接続部にはキンク防止用の補強チューブ28が設けられている。

【0026】図3と図4は融着方法を示す部分新面図で ある。図3は外管2の本体部分21と先端部分22の融 着に関し、図4は外管2の先端部分22と拡張体3の蒸 端部32の融着に関するものである。

【0027】両図を用いて、融着方法について説明する。

【0028】1. 外管2の先端部分22に金属の芯金50(直径0.75mm、ステンレス線(SUS30)4))を通した後、本体部分21の一部を重ね合わせるように本体部分21を芯金50に被せる。この重なった部分が散着しる25となる。

【0029】2. 続いて融着しろ25の部分を覆うよう にシリコーン製敷収縮チューブ26を被せ、シリコーン 製熱収縮チューブ26の上から加熱(130~140℃ で約10秒)する。シリコーン製熱収縮チューブ26は 熱収縮して融着しる25を強く密着させた状態で、加熱 配着されるので、強い機補塊度を持つ融資部が得られる。(図3等間)

40 3. 次に先端節分22の先端に、拡張体3の基端節32 を重ね合わせ、重ね合わせ部分を融着しる27とし、さらにシリコーン製熱収縮チューブ26を独せた後、加熱する。上記2と同様にシリコーン製熱収縮チューブ26は熱収縮して融着しる27を強く密着させた状態で加熱なある。(図4参照)

また、加熱融著の際に外管2の本体部分21の融着に関 与しない部分や、拡張体3の拡張部が熱的影響を受けないようにするために保護チューブ29を被せておくとよ 50 い。 【0030】4. 融着後、シリコーン製熱収縮チューブ 26、26を取り除く。

【0031】このようにして外管2と拡張体3を接続した後、続いて内管1の充端13と拡張体3の先端部31 を接続する。内管1は高密度ボリエチレン樹脂からなり、内管1に窓金(0.4mmステンレス線(SUS304))を通した状態で、拡張体3の先端部31と内管1の先端13を重ねたわせ、シリコーン製剤収縮チューブを被せたのち、加熱(130~140°で約20秒)する。熟収穫して圧縮された状態で融着される。

【0032】続いて、外管2の本体部分22の基端から 補強チューブ28を被せた後、そして、ハブ4を第1の 同日部41が第1のルーメン14と、第2の開口部42 と第2のルーメン24とが遊击するように接続して本体 部分220基端に固定し、最後に補強チューブ28をス ライドさせて、ハブに覆いかふさるようにして固定(接 着)する。

【0033】以上のようにして、拡張体付カテーテル1 のが作成される。作成された拡張体付カテーテル10は 拡張体3の基端部32と外管2の先端部分22は互いに 20 相溶性があり、確実に融着でき、リーク等の恐れがなく なる。

[0034]

【実施例2】第2の実施例について説明する。図5は第 2の実施例にかかる拡張体付カテーテルの部分断面図で ある。

[0035] 図5に示すように、第1の実施例の拡張体 付カテーデル10の外管2の内部には超弾性金属メイプ 50からなる補強体が入っている構造である。補強体5 0は直径1.0mmで厚みが0.07mmで、先端から 全長の3分の1まではコイル状になっており、先端付近 のピッチは0.5mmぐらいであり、基端方向に向けて 核々にピッチが広がっている。

【0036】作成方法について述べる。

[0037] 1. 先端から500mmまで、コイル状 (先端 (コイルビッチ0.5mm) から基端に向けてコ イルビッチが拡大している)をしているチタンニッケル 合金からなる超弾性パイプ50(全長約1m50cm、 直径1.0mm厚さ0.07mm)を準備する。続い

【0038】この後の第2実施例の作成方法は第1の実 施例と同様である。第2の実施例は第1の実施例とは外 管の本体部分21が異なるだけで、他の作成方法及び構 50 成は同じとなる。

[0039] 第2の実施例は補強体(超弊性バイブラ の) が入っているために、耐キンク性にすぐれ、また 見 好なトルク伝達性を示す。さらに先端部分は構造体が入 っていないので、柔軟性が高くなり、また、本体部分よ り、網ぐ形成でき、思曲波が高く細い適用部位でも高い 操作性を得ることができる。

【0040】また本実施例では、外管の本体部分21と 先蝶部分22とを先に融着したが、拡張体3の基端部3 10 2と先端部分22を先に融着しても良い。

[0041]

【発明の効果】本発明の拡張体付カテーテルは基端部と 先端部を有し、先端が開口する第1のルーメンを有する 内管と、該内管に同軸的に設けられ、本体部分と先端部 分と有し、該内管の先端より所定長後退した位置に設け られ、該内管の外面との間に第2のルーメンを形成し、 該先端部分は未架橋オレフィン系樹脂、該本体部分は架 橋オレフィン系樹脂からなり、該先端部分と該本体部分 は融着接続されている外管と、先端部および基端部を有 し、該基端部は前記外管の先端部分と融着接続され、該 先端部は前配内管に取り付けられ、該基端部付近にて前 記第2ルーメンと連通する収縮あるいは折り畳み可能な 架橋オレフィン系樹脂からなる拡張体と、該内管の基端 部に設けられた前配第1のルーメンと連通する第1の開 口部と、前記外管の本体部分の基端に設けられた前記第 2のルーメンと連通する第2の開口部とを有するため に、拡張体と外管との確実な接続が行われ、融着部にお けるリーク等の虞れがなくなる。

【0042】また、本発明の拡張体付カテーテルは前記外管の本体部分の内側に金属構造体を設けたことにより、耐キンク性やトルク伝達性に優れ。さらに、先端的分はチューブのみなので押く形成でき、また特別に柔軟性にすることも可能であり、屈曲が激しく、細い血管においても操作性が良好である。 さらに、本発回を拡張体付カテーテルは前記金属構造体は音状であり、先端部がゴイル状であることから、構強体は先端部が基端部に比べて柔軟になっており、カラーデル全長にわたって基準から先端に向けて柔軟性を高めることができる。

【図面の簡単な説明】

(0 【図1】図1は本発明の拡張体付カテーテルの全体図である。

【図2】図2は本発明の拡張体付カテーテルの拡張体が 付いた先端部分の拡大部分断面図である。

【図3】図3は外管の本体部分と先端部分の融着方法を 説明するための図である。

【図4】図4は外管の先端部分と拡張体の基端部の融着 方法を説明するための図である。

【図5】図5は本発明の第2の実施例にかかる拡張体付 カテーテルの部分断面図である。

【図6】図6は従来の拡張体付カテーテルの拡張体の取

105・・・基端部

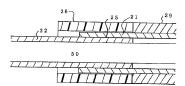
106, 107・・・融着しろ

り付け部を示す。 24・・・第2のルーメン 【符号の説明】 25, 27・・・融着しろ 10・・・拡張体付カテーテル 26・・・シリコーン製熱収縮チューブ 1 · · · 内管 1 28・・・補強チューブ 2・・・外管 29・・・保護チューブ 3・・・拡張体 31・・・先端部 4・・・ハブ 32・・・基端部 12・・・先端部 41,42 · · · 開口部 13・・・先端 50・・・芯金 14・・・第1のルーメン 10 101 · · · 内管101 15 · · · X線造影マーカー 102・・・外管102 21・・・本体部分 103・・・拡張体

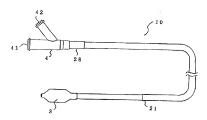
22・・・先端部分

23・・・後退した位置

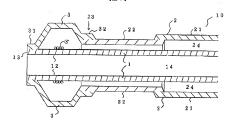
[図1]



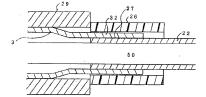
【図2】



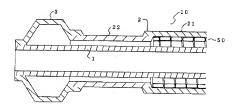




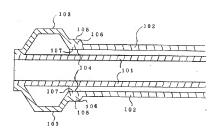
[図4]



[図5]



[図6]



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CLAIMS

[Claim(s)]

[Claim 1]A catheter with an expansion body characterized by comprising the following. An inner tube which has a base end and a tip part and has the 1st lumen in which a tip carries out an opening.

Are provided in this inner tube in same axle, and have with a body part and a tip end part, and it is provided in a position which carried out specified length retreat from a tip of this inner tube, An outer tube by which the 2nd lumen is formed between outside surfaces of this inner tube, as for this tip end part, unconstructed bridge olefin system resin and this body part consist of bridge construction olefin system resin, and fusion splicing is carried out as for this tip end part and this body part.

An expansion body which consists of bridge construction olefin system resin which it has a tip part and a base end, fusion splicing of this base end is carried out to a tip end part of said outer tube, and this tip part is attached to said inner tube, and is open for free passage with said 2nd lumen near [this] a base end, and in which contraction or folding is possible. Said 1st lumen provided in a base end of this inner tube, the 1st opening open for free passage, and said 2nd lumen provided in a end face of a body part of said outer tube and the 2nd opening open for free passage.

[Claim 2]The catheter with an expansion body according to claim 1 providing a metal reinforcement body inside a body part of said outer tube.

[Claim 3]The catheter with an expansion body according to claim 2, wherein said metal reinforcement body is tubular and a tip part is a coiled form.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Industrial Application]This invention relates to the catheter with an expansion body used for the technique inserted and extended to the strangulation part of the heart artery used as causes, such as myocardial infarction.

[0002]

[Description of the Prior Art]As a catheter with an expansion body which extends the narrow segment in the conventional blood vessel, there are some which are shown in JP,3-73167,A, for example. The attachment state of the expansion body of a catheter with an expansion body given in this gazette, The outer tube 102 provided in same axle with the inner tube 101 and this inner tube 101 as shown in <u>drawing 6</u>, consist of the expansion body 103 attached to the inner tube 101 and the outer tube 102, and the tip 104 of the outer tube 102 and the base end 105 of the expansion body 103 should weld connection of the outer tube 102 and the expansion body 103 — it is welding by heating, where 107 is piled up, 106 and. [0003]

[Problem(s) to be Solved by the Invention]In the above-mentioned catheter, the fusing strength of an outer tube and an expansion body might change a lot according to both construction material. The bridge may be constructed over the expansion body and outer tube which consist of olefin system resin in order to raise pressure resistance. However, when the construction material which consist of such bridge construction olefin system resin was pasted up by weld, high fusing strength could not be expected but there was a possibility that leak etc. might occur.

[0004]This invention does not have fear, such as leak resulting from such low fusing strength, and let it be SUBJECT to provide the catheter with an expansion body of pressure resistance. [0005]

[Means for Solving the Problem]This SUBJECT is solved by a catheter with an expansion body of this invention shown in the following (1) - (3).

[0006](1) An inner tube which has a base end and a tip part and has the 1st lumen in which a tip carries out an opening, Are provided in this inner tube in same axle, and have with a body part and a tip end part, and it is provided in a position which carried out specified length retreat from a tip of this inner tube, An outer tube by which the 2nd lumen is formed between outside surfaces of this inner tube, as for this tip end part, unconstructed bridge olefin system resin and this body part consist of bridge construction olefin system resin, and fusion splicing is carried out as for this tip end part and this body part, Have a tip part and a base end and fusion splicing of this base end is carried out to a tip end part of said outer tube, An expansion body which consists of bridge construction olefin system resin which this tip part is attached to said inner tube, and is open for free passage with said 2nd lumen near [this] a base end, and in which contraction or folding is possible, A catheter with an expansion body which has said 1st lumen provided in a base end of this inner tube, the 1st opening open for free passage, and said 2nd lumen provided in a end face of a body part of said outer tube and the 2nd opening open for free passage.

[0007](2) A catheter with an expansion body given in the above (1) which provided a metal reinforcement body inside a body part of said outer tube.

[0008](3) A catheter with an expansion body given in the above (2) whose tip part said metal reinforcement body is tubular and is a coiled form.

[0009]A tip end part of an outer tube which a catheter with an expansion body of this invention becomes from a base end and bridge construction olefin system resin of an expansion body which consists of bridge construction olefin system resin like the above (1) is connected by weld. As compared with bridge construction olefins, such fusion splicing has high compatibility and can realize firm weld. Adhesion of a body part and a tip end part consists of weld of bridge construction olefin system resin and unconstructed bridge olefin system resin similarly, and an outer tube serves as firm weld, and via a tip end part of unconstructed bridge olefin system resin, although it is indirect, It becomes possible to connect firmly an outer tube of bridge construction olefin system resin, and an expansion body of bridge construction olefin system resin.

[0010]What constructed the bridge slightly is included here unconstructed bridge olefin system resin not only shows a non-bridging body of olefin system resin, but, and what has a degree of cross linking lower than bridge construction olefin system resin is included.

[0011]Such fusion splicing is realizable as follows.

[0012]1. Lay a part of body part of through and bridge construction olefin system resin on top of a tip end part of an outer tube of unconstructed bridge olefin system resin for metaled rodding. This overlapping portion is should weld.

[0013]2. Put heat-shrinkable tubing made from silicone so that it continues, and it may weld and a portion of ** may be covered, and heat from heat-shrinkable tubing made from silicone. Since heat-shrinkable tubing made from silicone is heated where it carried out heat contraction, it welded and ** is stuck strongly, strong fusing strength is obtained. [0014]3. Heat after piling up a base end of an expansion body, supposing "Weld a superposition part" and putting heat-shrinkable tubing made from silicone at a tip of a tip end part further next. A terminal area of strong fusing strength is obtained like the above 2. [0015]Thus. It is easily realizable of high connection of fusing strength.

[0016]Next, since a metal reinforcement body was provided inside a body part of an outer tube like the above (2), torque convectivity is also high and the pushing characteristic also improves.

[0017]A reinforcement body is made tubular like the above (3), and a tip comes to be excellent in kink-proof nature by having considered it as a coiled form. As a method of forming in an outer tube, such a reinforcement body, A larger thing than a coil is beforehand prepared for a path of an outer tube, and if it heats after inserting a coil into this outer tube (however, a coil is not inserted in order that a predetermined portion may presuppose from a tip "weld"), an outer tube will be in the state where contracted and it stuck to an outside surface of a coil. When an outer tube and a reinforcement body stick thoroughly, it excels in torque convectivity, and kink-proof nature also improves and it comes to excel in operativity.

[0018]

[Example] Hereafter, with reference to the example of this invention, the contents of the invention are explained in detail.

[0019]

[Work example 1] Drawing 1 is the general drawing of the catheter 10 with an expansion body of this invention. Drawing 2 is the expansion part sectional view of a tip end part to which the expansion body of the catheter 10 with an expansion body was attached.

[0020]As shown in a figure, the catheter 10 with an expansion body consists of the inner tube 1, the outer tube 2, the expansion body 3, and the hub 4 provided in the end face. [0021]The inner tube 1 is a product made from high density polyethylene the thickness of 0.075 mm, and 1500 mm in length in 0.6 mm in diameter, and in order to have a base end and the tip part 12, to have the 1st lumen 14 in which the tip 13 carries out an opening and to show the position of the expansion body 3, the X ray imaging marker (platina coil) 15 is established. [0022]The outer tube 2 is formed in the inner tube 1 in same axle, and has with the body part 21 and the tip end part 22, it is 1270 mm in length, 0.9 mm in 1.07 mm in diameter of a body part, and diameter of a tip end part, and 80 mm in length, and both thickness is 0.075 mm. It is

provided in the position 23 which carried out specified length retreat from the tip 13 of the inner tube 1, and the 2nd lumen 24 is formed between the inner surfaces of the outer tube 2. The tip

end part 22 consists of unconstructed bridge olefin system resin (linear low density polyethylene (ethylene-hexene copolymer ($C_{\rm g}$ LLDPE))), The body part 21 consists of bridge construction olefin system resin (electron beam bridge construction article of linear low density polyethylene (ethylene-hexene copolymer ($C_{\rm g}$ LLDPE))), and fusion splicing of both is carried out.

[0023]The expansion body 3 has the tip part 31 and the base end 32, and fusion splicing of the base end 32 is carried out to the tip end part 22 of the outer tube 2, Fusion splicing of the tip part 31 is carried out at the tip 13 of the inner tube 1, It consists of bridge construction olefin system resin (electron beam bridge construction article of linear low density polyethylene (ethylene-hexene copolymer (C₆LLDPE))) which has an extension in which the 2nd lumen of 24, contraction open for free passage, or folding is possible in the base end 32 neighborhood. The base end 32 is 0.7 mm in outer diameter, is 0.15 mm in thickness, and is 1 mm in outer diameter, and the tip part 31 is 0.12 mm in thickness. An outer diameter when it extends is 2.5 mm, and an extension is 0.03 mm in thickness. The overall length of an expansion body is 27 mm. By the part applied, the size of an expansion body can be changed arbitrarily.

[0024]And the hub 4 has said 1st lumen 14 provided in the base end of the inner tube 1, the 1st opening 41 open for free passage, and the 2nd lumen 24 provided in the end face of the body part 21 of the outer tube 2 and the 2nd opening 42 open for free passage.

[0025]The armored tube 28 for kink prevention is prepared for the terminal area of the end face of the hub 4 and the body part 21 of the outer tube 2.

[0026] Drawing 3 and drawing 4 are the fragmentary sectional views showing a fusion method. As for drawing 4, drawing 3 is related with weld of the tip end part 22 of the outer tube 2, and the base end 32 of the expansion body 3 about weld of the body part 21 and the tip end part 22 of the outer tube 2.

[0027]A fusion method is explained using both figures.

[0028]1. After letting the metaled rodding 50 (mm [in diameter / 0.75], stainless lines (SUS304)) pass to the tip end part 22 of the outer tube 2, put the body part 21 on the rodding 50 so that a part of body part 21 may be piled up. this overlapping portion should weld — it is set to 25.

[0029]2. weld continuously — the portion of 25 — a wrap — put the heat-shrinkable tubing 26 made from silicone like, and heat from the heat-shrinkable tubing 26 made from silicone (it is about 10 seconds at 130-140 **). carry out heat contraction of the heat-shrinkable tubing 26 made from silicone, and weld it — it is in the state where 25 was stuck strongly, and since heating weld is carried out, a fuse section with strong fusing strength is obtained. (Refer to drawing 3)

3. next, pile up the base end 32 of the expansion body 3 at the tip of the tip end part 22, and

weld a superposition part to it — heat after being referred to as 27 and putting the heat-shrinkable tubing 26 made from silicone further. like the above 2, carry out heat contraction of the heat-shrinkable tubing 26 made from silicone, and weld it — since it is heated where 27 is stuck strongly, the fuse section of strong fusing strength is obtained. (Refer to drawing 4) In order that neither the portion which does not participate in weld of the body part 21 of the outer tube 2 in the case of heating weld, nor the extension of the expansion body 3 may receive thermal effect, it is good to put the protective tubing 29.

[0030]4. Remove the heat-shrinkable tubing 26 and 26 made from silicone after weld. [0031]Thus, after connecting the expansion body 3 with the outer tube 2, the tip 13 of the inner tube 1 and the tip part 31 of the expansion body 3 are connected continuously. After the inner tube 1 consists of high-density-polyethylene resin, is in the state which let rodding (0.4-mm stainless lines (SUS304)) pass to the inner tube 1, piles up the tip part 31 of the expansion body 3, and the tip 13 of the inner tube 1 and puts the heat-shrinkable tubing made from silicone, it is heated (it is about 20 seconds at 130-140 **). It is welded in the state where carried out heat contraction and it was compressed.

[0032]then, after putting the armored tube 28 from the end face of the body part 22 of the outer tube 2, The armored tube 28 is made to slide finally, it connects so that the lumen 14, and the 1st opening 42 and 2nd lumen 24 may open the hub 4 for free passage in the 1st opening 41, it fixes to the end face of the body part 22, it covers, and as it hangs over a hub, it fixes to it (adhesion). [2nd]

[0033]The catheter 10 with an expansion body is created as mentioned above. The base end 32 of the expansion body 3 and the tip end part 22 of the outer tube 2 have compatibility mutually, and can be welded certainly, and, as for the created catheter 10 with an expansion body, their fear, such as leak, disappears.

[0034]

[Work example 2]The 2nd example is described. <u>Drawing 5</u> is a fragmentary sectional view of the catheter with an expansion body concerning the 2nd example.

[0035]As shown in <u>drawing 5</u>, it is the structure where the reinforcement body which consists of the superelasticity metallic pipe 50 is contained in the inside of the outer tube 2 of the catheter 10 with an expansion body of the 1st example. Thickness is 0.07 mm in 1.0 mm in diameter, a tip to 1/3 of the overall length is a coiled form, the pitch near a tip is only 0.5 mm and, as for the reinforcement body 50, the pitch is spreading gradually towards the direction of a end face.

[0036]A preparation method is described.

[0037]1. Prepare the superelasticity pipe 50 (about 1 m cm [in overall length / 50], and 1.0-mm0.07 mm in thickness in diameter) which consists of a titanium nickel alloy which is carrying out the coiled form (the coil pitch is expanded towards a end face from the tip (0.5 mm of coil

pitches)) from a tip to 500 mm. It continues, The tube for outer-tube main part formation (1.05 mm in inside diameter) which consists of bridge construction olefin system resin (electron beam bridge construction article of linear low density polyethylene (ethylene-hexene copolymer (C₆LLDPE))) is put on the superelasticity pipe 50, where a pipe tip is retreated about 5 mm from the tip of an outer-tube main part. Heat after this, the diameter is made to reduce and the superelasticity pipe 50 and the tube for outer-tube main part formation are stuck. the portion of the resin simple substance removed after this -- the tip end part 22 -- weld -- it is set to 25.

[0038]The preparation method of the 2nd next example is the same as that of the 1st example. The 2nd example only differs in the body part 21 of an outer tube from the 1st example, and other preparation methods and composition become the same.

[0039]Since the reinforcement body (superelasticity pipe 50) is contained, the 2nd example is excellent in kink-proof nature, and shows good torque convectivity. Furthermore, since the reinforcement body is not contained, pliability can become high, and a tip end part can be formed more thinly than a body part, and can acquire high operativity even in the application site where a zigzag coefficient is high and thin.

[0040]In this example, although the body part 21 and the tip end part 22 of the outer tube were welded previously, the base end 32 and the tip end part 22 of the expansion body 3 may be welded first.

[0041]

[Effect of the Invention] The inner tube which the catheter with an expansion body of this invention has a base end and a tip part, and has the 1st lumen in which a tip carries out an opening. Are provided in this inner tube in same axle, and have with a body part and a tip end part, and it is provided in the position which carried out specified length retreat from the tip of this inner tube. The outer tube by which the 2nd lumen is formed between the outside surfaces of this inner tube, as for this tip end part, unconstructed bridge olefin system resin and this body part consist of bridge construction olefin system resin, and fusion splicing is carried out as for this tip end part and this body part, Have a tip part and a base end and fusion splicing of this base end is carried out to the tip end part of said outer tube. The expansion body which consists of bridge construction olefin system resin which this tip part is attached to said inner tube, and is open for free passage with said 2nd lumen near [this] a base end, and in which contraction or folding is possible. Since it has said 1st lumen provided in the base end of this inner tube, the 1st opening open for free passage, and said 2nd lumen provided in the end face of the body part of said outer tube and the 2nd opening open for free passage, positive connection between an expansion body and an outer tube is made, and fear, such as leak in a fuse section, is lost.

[0042]When the catheter with an expansion body of this invention provided the metal

reinforcement body inside the body part of said outer tube, It is also possible to excel in kink-proof nature or torque convectivity, to be able to form thinly further, since a tip end part is only a tube, and to make it pliability specially, crookedness is intense, and operativity is good also in a thin blood vessel. Said metal reinforcement body of the catheter with an expansion body of this invention is tubular, since the tip part is a coiled form, the tip part is flexible compared with the base end, and the reinforcement body can improve pliability towards a tip covering a catheter overall length from a end face.

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TECHNICAL FIELD

[Industrial Application]This invention relates to the catheter with an expansion body used for the technique inserted and extended to the strangulation part of the heart artery used as causes, such as myocardial infarction.

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PRIOR ART

[Description of the Prior Art]As a catheter with an expansion body which extends the narrow segment in the conventional blood vessel, there are some which are shown in JP,3-73167,A, for example. The attachment state of the expansion body of a catheter with an expansion body given in this gazette, The outer tube 102 provided in same axle with the inner tube 101 and this inner tube 101 as shown in drawing-6, consist of the expansion body 103 attached to the inner tube 101 and the outer tube 102, and the tip 104 of the outer tube 102 and the base end 105 of the expansion body 103 should weld connection of the outer tube 102 and the expansion body 103 — it is welding by heating, where 107 is piled up, 106 and.

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EFFECT OF THE INVENTION

[Effect of the Invention] The inner tube which the catheter with an expansion body of this invention has a base end and a tip part, and has the 1st lumen in which a tip carries out an opening. Are provided in this inner tube in same axle, and have with a body part and a tip end part, and it is provided in the position which carried out specified length retreat from the tip of this inner tube, The outer tube by which the 2nd lumen is formed between the outside surfaces of this inner tube, as for this tip end part, unconstructed bridge olefin system resin and this body part consist of bridge construction olefin system resin, and fusion splicing is carried out as for this tip end part and this body part. Have a tip part and a base end and fusion splicing of this base end is carried out to the tip end part of said outer tube, The expansion body which consists of bridge construction olefin system resin which this tip part is attached to said inner tube, and is open for free passage with said 2nd lumen near [this] a base end, and in which contraction or folding is possible. Since it has said 1st lumen provided in the base end of this inner tube, the 1st opening open for free passage, and said 2nd lumen provided in the end face of the body part of said outer tube and the 2nd opening open for free passage, positive connection between an expansion body and an outer tube is made, and fear, such as leak in a fuse section, is lost.

[0042]When the catheter with an expansion body of this invention provided the metal reinforcement body inside the body part of said outer tube, It is also possible to excel in kink-proof nature or torque convectivity, to be able to form thinly further, since a tip end part is only a tube, and to make it pliability specially, crookedness is intense, and operativity is good also in a thin blood vessel. Said metal reinforcement body of the catheter with an expansion body of this invention is tubular, since the tip part is a coiled form, the tip part is flexible compared with the base end, and the reinforcement body can improve pliability towards a tip covering a catheter overall length from a end face.

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TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention]In the above-mentioned catheter, the fusing strength of an outer tube and an expansion body might change a lot according to both construction material. The bridge may be constructed over the expansion body and outer tube which consist of olefin system resin in order to raise pressure resistance. However, when the construction material which consist of such bridge construction olefin system resin was pasted up by weld, high fusing strength could not be expected but there was a possibility that leak etc. might occur.

[0004]This invention does not have fear, such as leak resulting from such low fusing strength, and let it be SUBJECT to provide the catheter with an expansion body of pressure resistance.

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MEANS

[Means for Solving the Problem]This SUBJECT is solved by a catheter with an expansion body of this invention shown in the following (1) - (3).

[0006](1) An inner tube which has a base end and a tip part and has the 1st lumen in which a tip carries out an opening, Are provided in this inner tube in same axle, and have with a body part and a tip end part, and it is provided in a position which carried out specified length retreat from a tip of this inner tube, An outer tube by which the 2nd lumen is formed between outside surfaces of this inner tube, as for this tip end part, unconstructed bridge olefin system resin and this body part consist of bridge construction olefin system resin, and fusion splicing is carried out as for this tip end part and this body part, Have a tip part and a base end and fusion splicing of this base end is carried out to a tip end part of said outer tube, An expansion body which consists of bridge construction olefin system resin which this tip part is attached to said inner tube, and is open for free passage with said 2nd lumen near [this] a base end, and in which contraction or folding is possible, A catheter with an expansion body which has said 1st lumen provided in a base end of this inner tube, the 1st opening open for free passage, and said 2nd lumen provided in a end face of a body part of said outer tube and the 2nd opening open for free passage.

[0007](2) A catheter with an expansion body given in the above (1) which provided a metal reinforcement body inside a body part of said outer tube.

[0008](3) A catheter with an expansion body given in the above (2) whose tip part said metal reinforcement body is tubular and is a coiled form.

[0009]A tip end part of an outer tube which a catheter with an expansion body of this invention becomes from a base end and bridge construction olefin system resin of an expansion body which consists of bridge construction olefin system resin like the above (1) is connected by weld. As compared with bridge construction olefins, such fusion splicing has high compatibility and can realize firm weld. Adhesion of a body part and a tip end part consists of weld of bridge

construction olefin system resin and unconstructed bridge olefin system resin similarly, and an outer tube serves as firm weld, and via a tip end part of unconstructed bridge olefin system resin, although it is indirect, It becomes possible to connect firmly an outer tube of bridge construction olefin system resin, and an expansion body of bridge construction olefin system resin.

[0010]What constructed the bridge slightly is included here unconstructed bridge olefin system resin not only shows a non-bridging body of olefin system resin, but, and what has a degree of cross linking lower than bridge construction olefin system resin is included.

[0011]Such fusion splicing is realizable as follows.

[0012]1. Lay a part of body part of through and bridge construction olefin system resin on top of a tip end part of an outer tube of unconstructed bridge olefin system resin for metaled rodding. This overlapping portion is should weld.

[0013]2. Put heat-shrinkable tubing made from silicone so that it continues, and it may weld and a portion of ** may be covered, and heat from heat-shrinkable tubing made from silicone. Since heat-shrinkable tubing made from silicone is heated where it carried out heat contraction, it welded and ** is stuck strongly, strong fusing strength is obtained.

[0014]3. Heat after piling up a base end of an expansion body, supposing "Weld a superposition part" and putting heat-shrinkable tubing made from silicone at a tip of a tip end part further next. A terminal area of strong fusing strength is obtained like the above 2.

[0015] Thus, it is easily realizable of high connection of fusing strength.

[0016]Next, since a metal reinforcement body was provided inside a body part of an outer tube like the above (2), torque convectivity is also high and the pushing characteristic also improves.

[0017]A reinforcement body is made tubular like the above (3), and a tip comes to be excellent in kink-proof nature by having considered it as a coiled form. As a method of forming in an outer tube, such a reinforcement body, A larger thing than a coil is beforehand prepared for a path of an outer tube, and if it heats after inserting a coil into this outer tube (however, a coil is not inserted in order that a predetermined portion may presuppose from a tip "weld"), an outer tube will be in the state where contracted and it stuck to an outside surface of a coil. When an outer tube and a reinforcement body stick thoroughly, it excels in torque convectivity, and kink-proof nature also improves and it comes to excel in operativity.

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FXAMPLE

[Example]Hereafter, with reference to the example of this invention, the contents of the invention are explained in detail.

[0019]

[Work example 1] <u>Drawing 1</u> is the general drawing of the catheter 10 with an expansion body of this invention. <u>Drawing 2</u> is the expansion part sectional view of a tip end part to which the expansion body of the catheter 10 with an expansion body was attached.

[0020]As shown in a figure, the catheter 10 with an expansion body consists of the inner tube 1, the outer tube 2, the expansion body 3, and the hub 4 provided in the end face.

[0021]The inner tube 1 is a product made from high density polyethylene the thickness of 0.075 mm, and 1500 mm in length in 0.6 mm in diameter, and in order to have a base end and the tip part 12, to have the 1st lumen 14 in which the tip 13 carries out an opening and to show the position of the expansion body 3, the X ray imaging marker (platina coil) 15 is established.

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DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]

[Drawing 1]Drawing 1 is the general drawing of the catheter with an expansion body of this invention.

[Drawing 2]Drawing 2 is the expansion part sectional view of a tip end part to which the expansion body of the catheter with an expansion body of this invention was attached. [Drawing 3]Drawing 3 is a figure for explaining the fusion method of the body part and tip end part of an outer tube.

[Drawing 4]Drawing 4 is a figure for explaining the fusion method of the tip end part of an outer tube, and the base end of an expansion body.

[Drawing 5]Drawing 5 is a fragmentary sectional view of the catheter with an expansion body concerning the 2nd example of this invention.

[Drawing 6]Drawing 6 shows the mounting part of the expansion body of the conventional catheter with an expansion body.

[Description of Notations]

- 10 ... Catheter with an expansion body
- 1 ... Inner tube 1
- 2 ... Outer tube
- 3 ... Expansion body
- 4 ... Hub
- 12 ... Tip part
- 13 ... Tip
- 14 The 1st lumen
- 15 ... X ray imaging marker
- 21 ... Body part
- 22 ... Tip end part

- 23 ... Position which retreated
- 24 ... The 2nd lumen
- 25, 27 ... Weld.
- 26 ... Heat-shrinkable tubing made from silicone
- 28 ... Armored tube
- 29 ... Protective tubing
- 31 ... Tip part
- 32 ... Base end
- 41, 42 ... Opening
- 50 ... Rodding
- 101 ... Inner tube 101
- 102 ... Outer tube 102
- 103 ... Expansion body
- 105 ... Base end
- 106.107 ... Weld.

